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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/921,060	08/29/97	ANDERSON D	012712-432

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BURNS DOANE SWECKER & MATHIS
P OBOX 1404
ALEXANDRIA VA 22313

EXAMINER	
SCHWADRON,R	

ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No. 08/921,060	Applicant(s) Anderson et al.
	Examiner Ron Schwadron, Ph.D.	Group Art Unit 1644

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-10 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-10 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

15. Claims 1-10 are under consideration.

16. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because It does not identify the citizenship of each inventor. The citizenship of Inventors Hanna and Newman has been omitted.

17. Applicants need to update the status of the US patent applications (eg. abandoned, allowed, etc.) disclosed in the specification. Applicant needs to change 07/9077691 to 07/977691 because this is the correct serial number for the application listed on page 1 of the specification, line 20.

18 The abstract of the disclosure is objected to because it does not disclose the claimed invention (eg. the method of claim 1). Correction is required. See MPEP § 608.01(b).

19. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title should indicate that the invention involves treatment of B cell lymphoma with anti-CD20 antibody and at least one chemotherapeutic agent.

20. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

21. Claims 3,8-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make

and/or use the invention.

It is apparent that the chimeric antiCD20 antibody C2B8 derived from the transfectoma transfected with the vector known as ATCC 69119 is required to practice the instant invention as cited in claims which recite this antibody. As a required element, the vector used to produce the aforementioned antibody must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If said antibody is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the instant vector. See 37 CFR 1.802.

The specification does not provide a repeatable method for obtaining the antibody produced by the transfectoma transfected with the vector known as ATCC 69119. While the sequences of said antibody are disclosed in the specification, there is no indication that the antibodies produced by a transfectoma transfected with the deposited vector would have the identical sequence. The claims read on a specific antibody produced by a transfectoma transfected with the vector known as ATCC 69119. Deposit of the vector producing the aforementioned antibody would satisfy the enablement requirements of 35 U.S.C. 112.

In addition, the identifying information set forth in 37 CFR 1.809 (d) should be added to the specification. See 37 CFR 1.801-1.809 for additional explanation of these requirements.

While the aforementioned vector has been deposited with the ATCC under conditions of the Budapest Treaty, applicants need to meet the requirements under 37 CFR 1.808. The requirements under 37 CFR 1.808 can be met by submission of an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability of the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

22. Claims 3,8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 8 are indefinite in the recitation of "C2B8" because it is unclear what this particular designation means or encompasses. A preferred substitution indicates using language supported in the specification that the antibody is produced by a transfectoma containing the vector ATCC 69119.

23. Regarding priority for the claimed inventions with regards to the application of prior art, the following comments are made. The claimed invention is not disclosed in parent application 07/978,891 and therefore priority is not extended to said application. Regarding 08/149099 (US Patent 5,736,137), the scope of the claimed inventions is not disclosed in said application and therefore priority with regards to the instant invention is the filing date of the instant invention. Regarding 08/149099, there is no disclosure in said application of the scope of claims 1 or 2 of the instant application wherein any "therapeutic anti-CD20 antibody" or any "chimeric anti-CD20 antibody" is used in a method comprising administering "at least one chemotherapeutic agent". Regarding claim 3, there is no disclosure in application 08/149099 of the claimed invention using C2B8 and "at least one chemotherapeutic agent". Regarding claims 4-6, there no disclosure in application 08/149099 of the claimed invention using any "therapeutic anti-CD20 antibody" in a method comprising using at least one chemotherapeutic agent wherein the agent is administered at the time period recited in the claims. Regarding claim 7, there is no disclosure in 08/149099 of the claimed method wherein the particular agents or "mixtures thereof" are used in combination with any "therapeutic anti-CD20 antibody". Regarding claim 8, there is no disclosure in parent application of the claimed method that uses a mixture of the chemotherapeutic agents recited in said claim in combination with C2B8 or that uses a "anti-CD20 antibody that results in substantial depletion of peripheral B cells" in combination with a mixture of the chemotherapeutic agents recited in said claim. Regarding claims 9 and 10, there is no disclosure in application of the use of the particular type of generic antibody recited in said claim in the claimed method.

24. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

25. Claims 1-4,6,7 are rejected under 35 U.S.C. § 102(e) as being anticipated by Anderson et al. (US Patent 5,736,137).

Regarding the inventors of US Patent 5,736,137, the inventorship is incorrectly listed on said patent. John Leonard was removed as an inventor of said application (see Paper 39 of 08/149099, also see inventors listed on file jacket of said application). Thus, US Patent 5,736,137 constitutes prior art under 35 U.S.C. § 102(e). Anderson et al. teach the use of C2B8 (a particular species of anti-CD20 therapeutic antibody) in combination with a chemotherapeutic agent wherein the agent is administered before or after C2B8 (see column 32), wherein the agent is one of the agents recited in claim 7.

26. Claims 1,2,4,5,7-10 are rejected under 35 U.S.C. § 102(e) as being anticipated by Kaminski et al. (US Patent 5,595,721).

Kaminski et al. teach the use of a "therapeutic anti-CD20" antibody (see abstract and column 5) for the treatment of B cell lymphoma. Kaminski et al. teach that said antibody can be chimeric (see column 7). Kaminski et al. teach that therapeutic anti-CD20 antibody was administered to patients that had received a mixture of the agents recited in claim 8 (see Table 1). Kaminski et al. teach the administration of therapeutic anti-CD20 antibody in combination with cyclophosphamide (see column 33). Kaminski et al. teach the use of therapeutic anti-CD20 antibody wherein said antibody depletes virtually all peripheral B cells within 24 hours(see column 19, first complete paragraph) wherein the dosage used is encompassed by the range recited in claim 10 (see Table 3).

27. Claims 1,4,7-10 are rejected under 35 U.S.C. § 102(b) as being anticipated by

Press et al. (J. Clin. Oncol.).

Press et al. teach the use of a "therapeutic anti-CD20" antibody (see abstract) for the treatment of B cell lymphoma. Press et al. teach that therapeutic anti-CD20 antibody was administered to patients that had received a mixture of the agents recited in claim 8 (see Table 1 and page 1033, second column)). Press et al. teach the use of therapeutic anti-CD20 antibody wherein said antibody depletes virtually all peripheral B cells within 24 hours(see column one, page 1035) wherein the dosage used is encompassed by the range recited in claim 10 (see page 1029, column 1).

28. Claims 1,4,7-10 are rejected under 35 U.S.C. § 102(b) as being anticipated by Press et al. (Blood).

Press et al. teach the use of a "therapeutic anti-CD20" antibody (see abstract) for the treatment of B cell lymphoma. Press et al. teach that therapeutic anti-CD20 antibody was administered to patients that had received a mixture of the agents recited in claim 8 (see page 586, column 1). Press et al. teach the use of therapeutic anti-CD20 antibody wherein said antibody depletes virtually all peripheral B cells within 24 hours(see Figure 2) wherein the dosage used is encompassed by the range recited in claim 10 (see page 590, column 1).

29. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

30. Claims 1,2,4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaminski et al. In view of Hellstrom et al. (WO 92/07466).

The claim is drawn to the method of claim 6. Kaminski et al. teach the use of a "therapeutic anti-CD20" antibody (see abstract and column 5) for the treatment of B cell lymphoma. Kaminski et al. teach that said antibody can be chimeric (see column 7). Kaminski et al. teach that therapeutic anti-CD20 antibody was administered to patients that

had received a mixture of the agents recited in claim 8 (see Table 1). Kaminski et al. teach the administration of therapeutic anti-CD20 antibody in combination with cyclophosphamide (see column 33). Kaminski et al. teach the use of therapeutic anti-CD20 antibody wherein said antibody depletes virtually all peripheral B cells within 24 hours(see column 19, first complete paragraph) wherein the dosage used is encompassed by the range recited in claim 10 (see Table 3). Kaminski et al. do not teach the method of claim 6. Hellstrom et al. teach that monoclonal antibody treatment in combination with chemotherapeutic agents can be used to treat cancer (see page 4). Hellstrom et al. teach that the chemotherapeutic agent can be administered after antibody treatment (see page 4). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Kaminski et al. teach the administration of therapeutic anti-CD20 antibody in combination with a chemotherapeutic agent, while Hellstrom et al. teach that monoclonal antibody treatment in combination with chemotherapeutic agents can be used to treat cancer (see page 4) and that the chemotherapeutic agent can be administered after antibody treatment. One of ordinary skill in the art would have been motivated to do the aforementioned because Hellstrom et al. teach the advantages of combined antibody/chemotherapy treatment for treating tumors (see page 4).

31. Claims 1,2,4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Press et al. (J. Clin. Oncol.) or Press et al. (Blood) in view of Hellstrom et al. (WO 92/07466) and Robinson et al. (US Patent 5,500,362).

The claims are drawn to the methods of claims 2,5 and 6. Press et al.(J. Clin. Oncol.) teach the use of a "therapeutic anti-CD20" antibody (see abstract) for the treatment of B cell lymphoma. Press et al.(J. Clin. Oncol.) teach that therapeutic anti-CD20 antibody was administered to patients that had received a mixture of the agents recited in claim 8 (see Table 1 and page 1033, second column)). Press et al. (J. Clin. Oncol.) teach the use of therapeutic anti-CD20 antibody wherein said antibody depletes virtually all peripheral B cells within 24 hours(see column one, page 1035) wherein the dosage used is encompassed by the range recited in claim 10 (see page 1029, column 1). Press et al. (Blood) teach the use of a "therapeutic anti-CD20" antibody (see abstract) for the treatment of B cell lymphoma. Press et al. (Blood) teach that therapeutic anti-CD20

antibody was administered to patients that had received a mixture of the agents recited in claim 8 (see page 586, column 1). Press et al. (Blood) teach the use of therapeutic anti-CD20 antibody wherein said antibody depletes virtually all peripheral B cells within 24 hours(see Figure 2) wherein the dosage used is encompassed by the range recited in claim 10 (see page 590, column 1). Neither Press et al. reference teaches the methods of claims 2,5 or 6. Hellstrom et al. teach that monoclonal antibody treatment in combination with chemotherapeutic agents can be used to treat cancer (see page 4). Hellstrom et al. teach that the chemotherapeutic agent can be administered at the same time as antibody treatment or after antibody treatment (see page 4). Hellstrom et al. teach the use of chimeric antibodies in combination with chemotherapy (see page 7). Robinson et al. teach chimeric anti-CD20 antibody (see abstract) and methods for making chimeric anti-CD20 antibodies. The chimeric antibodies taught by Robinson et al. could have been used in the claimed method or the methods taught by Robinson et al. could have been used to create chimeric versions of the antibodies taught by Press et al. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because both Press et al. references teach the use of antiCD20 antibody to treat B cell lymphoma, while Hellstrom et al. teach that monoclonal antibody treatment in combination with chemotherapeutic agents can be used to treat cancer wherein the chemotherapeutic agent can be administered at the same time as antibody treatment or after antibody treatment ,Hellstrom et al. teach the use of chimeric antibodies in combination with chemotherapy and Robinson et al. teach the use of chimeric antiCD20 antibody to treat B cell lymphoma. One of ordinary skill in the art would have been motivated to do the aforementioned because Hellstrom et al. teach that the chemotherapeutic agent can be administered at the same time as antibody treatment or after antibody treatment (see page 4). One of ordinary skill in the art would have been motivated to do the aforementioned because Hellstrom et al. teach the use of chimeric antibodies in combination with chemotherapy (see page 7) and Robinson et al. teach the use of chimeric anti-CD20 antibody for the treatment of B cell lymphoma (see column 20).

32. Claims 1,2,3,5,6,7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hellstrom et al. (WO 92/07466) in view of Reff et al. (J. Cell. Biochem.) or Anderson et al. or Reff et al. (Blood).

The claims are drawn to the methods of claims 1,2,3,5,6,7. Hellstrom et al. teach that monoclonal antibody treatment in combination with chemotherapeutic agents can be used to treat cancer (see page 4). Hellstrom et al. teach that the chemotherapeutic agent can be administered at the same time as antibody treatment or after antibody treatment (see page 4). Hellstrom et al. teach the use of chimeric antibodies in combination with chemotherapy (see page 7). Hellstrom et al. teach that the antibody used in the aforementioned method binds tumor cells. Hellstrom et al. do not teach that the use of chimeric antiCD20 antibody C2B8 in said method. Reff et al. (J. Cell. Biochem.) teach the chimeric antiCD20 antibody C2B8 and that said antibody binds B cell lymphomas (see entire document). Anderson et al. teach the chimeric antiCD20 antibody C2B8 and that said antibody binds B cell lymphomas (see entire document). Reff et al.(Blood) teach the chimeric antiCD20 antibody C2B8 and that said antibody binds B cell lymphomas (see entire document). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Hellstrom et al. teach that monoclonal antibody treatment in combination with chemotherapeutic agents can be used to treat cancer wherein the antibody used in the aforementioned method binds tumor cells, while Reff et al. (Blood) or Reff et al. (J. Cell. Biochem.) or Anderson et al. teach chimeric antiCD20 antibody C2B8 and that said antibody binds B cell lymphomas. One of ordinary skill in the art would have been motivated to do the aforementioned because Hellstrom et al. teach that the aforementioned method can be practiced with antibody that binds tumor cells. In addition, the Reff et al. or Anderson et al. references teach that C2B8 could be used to treat B cell lymphoma.

33. No claim is allowed.

34. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 305-3014.

35. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-

4680. The examiner can normally be reached Tuesday through Friday from 8:30 to 6:00. The examiner can also be reached on alternative Mondays. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644
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